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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,029	06/23/2003	Sureshchandra K. Patel		9566

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LAW OFFICES OF MARK E WIEMELT, PC
10 SOUTH LASALLE STREET, STE. 3300
CHICAGO, IL 60603

EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,029

Applicant(s)

PATEL, SURESHCHANDRA K.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0603</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are rendered vague and indefinite by the phrase "chemical composition" because this phrasing is typically used to denote compositions containing chemical compounds, *per se*. In addition, it is unclear by this phrase if the recited ingredients within the claimed composition have therapeutic activity. It is therefore suggested that the term "chemical" be replaced with --pharmaceutical--.

Claims 1-9 and 11-19 are rendered vague and indefinite because they fail to recite operative amounts of one or more the claimed herbal ingredients. Therefore, it is unclear if the herbal ingredients are the active agents within the composition, if they are merely some type of inert agent(s), and/or if they are present in very small amounts representing perhaps one or more contaminants or residues. The claimed herbal ingredients are each deemed to be essential elements of the instant invention and, as such, they should be clearly defined (functionally) in the claim language itself. It is, therefore, suggested that the phrase --for relieving headache...stomach acidity symptoms-- after the term "composition" in line 1 of claim 1; and that the phrase --effective amounts of-- be inserted after the word term "comprising" in line 1 of claim 1 and after the term "administering" in line 2 of claim 1.

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Claims 11 and 20 are rendered vague and indefinite because it is unclear as to who and/or what the composition is being orally administered to - e.g., --to a subject in need thereof--, or to someone else? Further, it is unclear in the method recited in claims 11 and 20 if such a subject is suffering from symptoms associated with all of the various ailments instantly claimed or if the subject is suffering from one or more of the recited ailments. In addition, it is unclear as to the actual definition of the disorder "blood constipation" - what does this mean?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art, in view of the Trifala IDS website references obtained from eisra.com (copyright 1998) and healthymagnets.com (first copyright 1999).

A composition comprising asafetida, ajwain seed, vidanga, cumin seeds, fenugreek, triphala, fennel seed, and turmeric is claimed, as well as a method of administering such a composition is claimed.

As readily admitted by Applicant, each of the claimed herbal ingredients (other than perhaps one of the three herbals found within triphala) is well known in the art to be useful in

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treating gastrointestinal disorders (e.g., indigestion, intestinal disorders, intestinal gas, regulating digestion, heartburn, dyspepsia) - see, e.g., pages 3-5 of the instant specification.

The cited triphala website references beneficially disclose that triphala is well known in the art to be useful in strengthening/regulating digestion and harmonizing intestinal functions - see entire website documents (in addition, although not relied upon at this time, it should be noted that several of the other website references provided in the IDS of June 23, 2003 disclose that one or more of the claimed herbal have traditionally been used in the prior art for such purpose - i.e., to treat gastrointestinal disorders).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., to treat gastrointestinal disorders) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore ipso facto unpatentable.

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Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill based upon the prior art knowledge of the claimed herbals, as discussed above. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of one of more of the claimed herbal ingredients therein and/or administering the composition to a subject for relief of such gastrointestinal disorders) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the admitted state of the art and cited website references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Christopher R. Tate', with a stylized, looping flourish above the name.

Christopher R. Tate
Primary Examiner
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